

REMARKS/ARGUMENTS

Claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 91, 97-101, 107, 132-144, and 147-155 have been examined. Claims 1, 2, 22, 84, and 101 have been amended. Claims 132-144 and 147 to 155 have been canceled. Re-examination and reconsideration of pending claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 91, 97-101, and 107 are respectfully requested.

Claim Objections

As requested by Examiner, Applicants have amended claims 2 and 101 to correct informalities. Claims 133, 137, and 139 have been canceled. Accordingly, withdrawal of these objections is respectfully requested.

Rejections Under 35 U.S.C. § 102

Independent claim 132 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,195,978 issued to Schiffer. Independent claim 132 has also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,395,335 issued to Jang. Applicants have canceled claims 132-144 and 147-155 without prejudice pursuant to re-filing claims of a similar scope in a related application.

Rejections Under 35 U.S.C. § 103

Independent claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,655,746 issued to Daniels et al. in view of U.S. Patent No. 5,135,535 issued to Kramer. Such a rejection is traversed in part and overcome in part as follows.

Independent claims 1 and 2 have been amended to expedite prosecution of the present case and more clearly claim the present invention. Claim 1 now recites an intravascular balloon catheter (10") comprising a catheter body (12) and a first balloon structure (14). The catheter body (12) has a proximal end, a distal end, and a guidewire lumen (20) therebetween. The first balloon structure (14) has a shaft (26), a passage (41) which is slidably receivable over

the catheter body (12) and receivable over the shaft (26), and an axial groove (102) along at least a portion of the structure (26) and the passage (41) to removably receive at least a portion of the catheter body (12). Claim 2 has been similarly amended.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. As the Examiner certainly knows and appreciates, the Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976). In the instant case, the Examiner has failed to establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. §2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). In particular, the distinctly claimed and separate axial groove limitation has not been shown or suggested in any of the cited art references, alone or in combination.

The Daniels et al. reference is directed at a catheter device as shown in Figure 3. Significantly, this reference fails to remotely teach or suggest any axial groove elements as required by claims 1 and 2. The Examiner further appears to agree that "Daniels fails to form the balloon structure shaft (16) to have an axial groove." Office Action, page 4. The Examiner then attempts to cure this deficiency with the Kramer reference by maintaining that:

Kramer discloses another balloon catheter that includes a first balloon structure shaft (11) that has a passage (14) that receives a guide wire (29). Kramer teaches that the shaft (11) should include an axial slit (23, 24), or groove, along the length of the shaft proximal to the balloon. The groove (23, 24) allows the balloon structure shaft (11, 13) to be removed from the guide wire (29) while the guide wire (29) remains stationary in the body lumen. A replacement catheter may then be subsequently delivered over the guide wire (see column 6, lines 22-48).

Id. Applicants respectfully disagree.

As illustrated in Figures 1-3 of the Kramer reference, a conventional rapid exchange over-the-wire balloon catheter (10) is shown for use with a guide wire (29), not a catheter body having a guide wire lumen as required by claims 1 and 2. The Kramer catheter (10) may have slits (23, 24), not axial grooves as required by claims 1 and 2, that allow for separation of the guide wire (29) from the guide wire lumen (14) of the catheter (10). ***More significantly, these slits described by Kramer fail to define an axial groove that extends along***

at least a portion of the passage, the passage being slidably receivable over the catheter body and receivable over the balloon structure shaft. The passage (14) in Kramer denoted by the Examiner above clearly fails to be receivable over the balloon structure shaft (11). In sum, this reference fails to teach or suggest the two distinct and separate elements of the claimed balloon structure (14), namely (a) a passage (41) being slidably receivable over the catheter body (12) and receivable over the balloon structure shaft (26) and (b) an axial groove (102), much less an axial groove (102) that extends along at least a portion of the passage (41).

Response to Advisory Action

The Examiner states that the

new limitation 'and shaft' raises 112 2nd paragraph issues. **The passage (defined by opening 104 in Figure 5B) of the balloon structure is not slidable relative to the shaft (26) of the balloon structure.** In fact, the passage is simply a lumen defined by the balloon structure shaft (26). For clarification, applicant has previously elected the embodiment of Figure 5A and 5B. Applicant's argument that the passage is defined by being slidable over both the catheter body and balloon structure shaft is not supported by the specification and is considered moot.

Advisory Action, page 2. Applicants have revised independent claims 1 and 2 to clearly recite that the "the passage is receivable over the catheter body." Applicants note however that the Examiner mischaracterizes the claimed passage (41) of the balloon structure (14). Element (104) shown in Fig. 5B defines the opening for the axial groove (102). The claimed sleeve passage (41) finds support in elected Fig. 5A (element 41 is clearly denoted in Fig. 1A). This passage (41) is clearly slidably receivable over the catheter body (12) and receivable over the balloon structure shaft (26).

Applicants request if the present rejection is maintained, the Examiner show or explain where the Kramer reference teaches or suggest the distinct structural limitation of an axial groove (102) that extend along at least a portion of the passage (41), wherein the passage (41) is defined by being slidably receivable over the catheter body (12) and receivable over the balloon structure shaft (26). Absent a showing in the cited art of record for this distinct and

structural difference, Applicants request the withdrawal of these rejections and allowance of independent claims 1 and 2 (and the claims which depend therefrom).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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